IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LEO PHARMA A/S, LEO LABORATORIES LIMITED, and LEO PHARMA, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
PERRIGO UK FINCO LIMITED PARTNERSHIP and PERRIGO COMPANY,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs LEO Pharma A/S ("LEO Pharma"), LEO Laboratories Limited ("LEO Labs"), and LEO Pharma, Inc. ("LEO, Inc.") (collectively, "LEO") by their attorneys, for their complaint against Perrigo UK Finco Limited Partnership ("Perrigo UK"), and Perrigo Company ("Perrigo Co.") (collectively, "Perrigo"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq*., and in particular under 35 U.S.C. § 271(a), (b), (c), and (e). This action relates to Abbreviated New Drug Application ("ANDA") Nos. 209018 and 209019 (collectively, "the Perrigo ANDAs"), filed by and for the benefit of Perrigo with the U.S. Food and Drug Administration ("FDA") seeking approval to market generic versions of LEO Pharma's PICATO® innovative pharmaceutical products, which are gels containing ingenol mebutate as the active pharmaceutical ingredient at dosage strengths of 0.015% and 0.05%.

THE PARTIES

2. Plaintiff LEO Pharma is a company organized and existing under the laws of Denmark with its headquarters at Industriparken 55, DK-2750 Ballerup, Denmark. LEO Pharma

is a research-based company dedicated to developing innovative drugs to help patients with dermatologic conditions.

3. Plaintiff LEO Labs is a company organized and existing under the laws of Ireland with its headquarters at 285 Cashel Road, Dublin 12, Ireland. LEO Labs is a wholly owned subsidiary of LEO Pharma.

4. Plaintiff LEO, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1 Sylvan Way, Parsippany, NJ 07054. LEO, Inc. is a wholly owned subsidiary of LEO Pharma.

5. On information and belief, Defendant Perrigo UK is a limited partnership organized and existing under the laws of the United Kingdom, with its principal place of business at Wrafton, Braunton, Devon, EX33 2DL, United Kingdom.

6. On information and belief, Perrigo UK is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within this judicial district, through its own actions, and through the actions of its agents and affiliates, including, at least, Perrigo Co.

7. On information and belief, Defendant Perrigo Co. is a corporation organized and existing under the laws of the State of Michigan, with its principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010.

8. On information and belief, Perrigo Co. is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including

within this judicial district, through its own actions, and through the actions of its agents and affiliates, including, at least, Perrigo UK.

9. On information and belief, Perrigo UK and Perrigo Co. are affiliates of each other, and are both subsidiaries of Perrigo Company plc.

10. On information and belief, Perrigo UK and Perrigo Co. each act as an agent of the other and work together to, *inter alia*, develop, manufacture, obtain regulatory approval, market, sell, and distribute generic copies of branded pharmaceutical products throughout the United States, including within this judicial district.

11. On information and belief, Perrigo Co. acts as Perrigo UK's U.S. agent, including, at least, with respect to the Perrigo ANDAs and the Paragraph IV notices associated with the Perrigo ANDAs.

12. On information and belief, Perrigo UK and Perrigo Co. participated and collaborated in the research and development, and the preparation and filing, of the Perrigo ANDAs, continue to participate and collaborate in seeking FDA approval of the Perrigo ANDAs, intend to participate and collaborate in the commercial manufacture, marketing offer for sale, and sale of Perrigo's ANDA Products throughout the United States including this judicial district, and stand to benefit from the approval of the Perrigo ANDAs.

JURISDICTION AND VENUE

13. This is a civil action for patent infringement arising under the patent laws of the United States of America, Title 35 of the U.S. Code, for infringement of U.S. Patent No. 6,432,452 ("the '452 Patent"), U.S. Patent No. 6,787,161 ("the '161 Patent"), U.S. Patent No. 6,844,013 ("the '013 Patent"), U.S. Patent No. 7,410,656 ("the '656 Patent"), U.S. Patent No. 8,278,292 ("the '292 Patent"), U.S. Patent No. 8,372,827 ("the '827 Patent"), U.S. Patent No. 8,372,828 ("the '828 Patent"), U.S. Patent No. 8,377,919 ("the '919 Patent"), U.S. Patent No.

8,536,163 ("the '163 Patent"), U.S. Patent No. 8,716,271 ("the '271 Patent"), and U.S. Patent No. 8,735,375 ("the '375 Patent") (collectively, "the Patents-in-Suit").

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

15. On information and belief, Perrigo Co. and Perrigo UK intend to sell Perrigo's proposed generic PICATO® products through retail outlets and wholesalers, as well as hospitals and pharmacies, in Delaware.

16. On information and belief, Perrigo Co. is directly responsible for sales of Perrigo products to customers in Delaware, from which Perrigo Co. derives substantial revenue.

17. On information and belief, Perrigo UK develops and manufactures pharmaceutical products for the United States market, and has developed and manufactured such products from which it derives substantial revenue from the sale of products to customers in Delaware.

18. On information and belief, Perrigo UK, directly or in concert with related companies, has engaged in substantial and continuous contacts with Delaware which satisfy due process and confer personal jurisdiction over Perrigo UK in Delaware on the basis of general jurisdiction.

19. On information and belief, Perrigo Co., directly or in concert with related companies, has engaged in substantial and continuous contacts with Delaware which satisfy due process and confer personal jurisdiction over Perrigo Co. in Delaware on the basis of general jurisdiction.

20. This Court also has personal jurisdiction over Perrigo UK and Perrigo Co. because they each have continuous and systemic contacts with Delaware. Further, both Perrigo

UK and Perrigo Co. have committed, or aided, abetted, contributed to and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to LEO, which manufactures PICATO® for sale and use throughout the United States, including in this judicial district. In addition, on information and belief, if the Perrigo ANDAs were to receive approval, Perrigo UK and Perrigo Co. would market and sell generic versions of PICATO® in Delaware.

21. This Court also has personal jurisdiction over Perrigo UK because Perrigo UK has availed itself of the legal protections of the State of Delaware by voluntarily submitting to and employing the jurisdiction of this Court as a counter-claimant.

22. This Court also has personal jurisdiction over Perrigo Co. because Perrigo Co. has availed itself of the legal protections of the State of Delaware by voluntarily submitting to and employing the jurisdiction of this Court as a counter-claimant.

23. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

LEO'S APPROVED PICATO® DRUG PRODUCTS AND PATENTS

24. LEO Pharma is the holder of New Drug Application ("NDA") No. 202833 for ingenol mebutate gel, 0.015% and 0.05%, which was approved by FDA on January 23, 2012. LEO Pharma and LEO, Inc. market the innovative approved drug products under the trade name PICATO®.

25. The active pharmaceutical ingredient in PICATO® is ingenol mebutate, also referred to as ingenol-3-angelate.

26. PICATO® is the first approved pharmaceutical product to contain the compound ingenol mebutate. In recognition of this, the FDA awarded PICATO® New Chemical Entity ("NCE") exclusivity, which expires January 23, 2017, pursuant to 21 C.F.R. § 314.108.

27. LEO Pharma's PICATO® products are approved for the topical treatment of actinic keratosis. A true and correct copy of the prescribing information for LEO Pharma's PICATO® products approved in NDA No. 202833 is attached as Exhibit A.

28. FDA has awarded PICATO® gel, 0.015%, additional exclusivity based on studies provided in a Supplemental NDA, which expires November 19, 2018.

29. The PICATO® products, and their use, are covered by claims of the '452 Patent, the '161 Patent, the '013 Patent, the '656 Patent, the '292 Patent, the '827 Patent, the '828 Patent, the '919 Patent, the '163 Patent, the '271 Patent, and the '375 Patent.

30. The Patents-in-Suit are listed in FDA's Orange Book—formally known as *Approved Drug Products With Therapeutic Equivalence Evaluations*—in connection with NDA No. 202833.

31. LEO Labs is the owner of, and has the right to enforce, the Patents-in-Suit.

32. The '452 Patent, entitled "Anti-Cancer Compounds," was duly and legally issued by the United States Patent and Trademark Office on August 13, 2002. The Orange Book presently shows that the '452 Patent's term ends on August 19, 2018. A true, correct, and complete copy of the '452 Patent is attached hereto as Exhibit B.

33. The '161 Patent, entitled "Anti-Cancer Compounds," was duly and legally issued by the United States Patent and Trademark Office on September 7, 2004. The Orange Book presently shows that the '161 Patent's term ends on August 19, 2018. A true, correct, and complete copy of the '161 Patent is attached hereto as Exhibit C.

34. The '013 Patent, entitled "Methods of Stimulating the Immune System," was duly and legally issued by the United States Patent and Trademark Office on January 18, 2005. The

Orange Book presently shows that the ’013 Patent’s term ends on December 13, 2018. A true, correct, and complete copy of the ’013 Patent is attached hereto as Exhibit D.

35. The ’656 Patent, entitled “Anti-Cancer Compounds,” was duly and legally issued by the United States Patent and Trademark Office on August 12, 2008. The Orange Book presently shows that the ’656 Patent’s term ends on October 10, 2020. A true, correct, and complete copy of the ’656 Patent is attached hereto as Exhibit E.

36. The ’292 Patent, entitled “Therapeutic Compositions,” was duly and legally issued by the United States Patent and Trademark Office on October 2, 2012. The Orange Book presently shows that the ’292 Patent’s term ends on July 6, 2027. A true, correct, and complete copy of the ’292 Patent is attached hereto as Exhibit F.

37. The ’827 Patent, entitled “Therapeutic Compositions,” was duly and legally issued by the United States Patent and Trademark Office on February 12, 2013. The Orange Book presently shows that the ’827 Patent’s term ends on December 18, 2026. A true, correct, and complete copy of the ’827 Patent is attached hereto as Exhibit G.

38. The ’828 Patent, entitled “Therapeutic Compositions,” was duly and legally issued by the United States Patent and Trademark Office on February 12, 2013. The Orange Book presently shows that the ’828 Patent’s term ends on December 18, 2026. A true, correct, and complete copy of the ’828 Patent is attached hereto as Exhibit H.

39. The ’919 Patent, entitled “Therapeutic Compositions,” was duly and legally issued by the United States Patent and Trademark Office on February 19, 2013. The Orange Book presently shows that the ’919 Patent’s term ends on December 18, 2026. A true, correct, and complete copy of the ’919 Patent is attached hereto as Exhibit I.

40. The ’163 Patent, entitled “Therapeutic Compositions,” was duly and legally issued by the United States Patent and Trademark Office on September 17, 2013. The Orange Book presently shows that the ’163 Patent’s term ends on December 18, 2026. A true, correct, and complete copy of the ’163 Patent is attached hereto as Exhibit J.

41. The ’271 Patent, entitled “Therapeutic Compositions,” was duly and legally issued by the United States Patent and Trademark Office on May 6, 2014. The Orange Book presently shows that the ’271 Patent’s term ends on December 18, 2026. A true, correct, and complete copy of the ’271 Patent is attached hereto as Exhibit K.

42. The ’375 Patent, entitled “Therapeutic Compositions,” was duly and legally issued by the United States Patent and Trademark Office on May 27, 2014. The Orange Book presently shows that the ’375 Patent’s term ends on December 18, 2026. A true, correct, and complete copy of the ’375 Patent is attached hereto as Exhibit L.

PERRIGO’S ANDA NO. 209018 AND ANDA NO. 209019

43. On information and belief, Perrigo has submitted or caused to be submitted ANDA No. 209018 to FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of Ingenol Mebutate gel, 0.015%, as a purported generic version of PICATO®, prior to the expiration of the Patents-in-Suit. On information and belief, Perrigo’s generic Ingenol Mebutate gel, 0.015%, is a formulation that comprises ingenol mebutate, also known as ingenol-3-angelate, as its active pharmaceutical ingredient.

44. On information and belief, Perrigo has also submitted or caused to be submitted ANDA No. 209019 to FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of Ingenol Mebutate gel, 0.05%, as a purported generic version of PICATO®, prior to the expiration of the Patents-in-Suit. On information and belief,

Perrigo's generic Ingenol Mebutate gel, 0.05%, is a formulation that comprises ingenol mebutate, also known as ingenol-3-angelate, as its active pharmaceutical ingredient.

45. LEO received a letter from Perrigo Co., dated April 29, 2016, representing that Perrigo UK had submitted to FDA ANDA No. 209018 with a Paragraph IV certification as against the Patents-in-Suit ("the 0.015% Notice Letter"). The purpose of the ANDA is to obtain FDA approval to engage in the commercial manufacture and sale of a generic version of LEO Pharma's PICATO® product before the expiration of the Patents-in-Suit.

46. LEO also received a letter from Perrigo Co., dated April 29, 2016, representing that Perrigo UK had submitted to FDA ANDA No. 209019 with a Paragraph IV certification as against Patents-in-Suit ("the 0.05% Notice Letter"). The purpose of the ANDA is to obtain FDA approval to engage in the commercial manufacture and sale of a generic version of LEO Pharma's PICATO® product before the expiration of the Patents-in-Suit.

47. Hence, Perrigo's purpose in submitting the Perrigo ANDAs is to gain approval from the FDA to manufacture and market generic Ingenol Mebutate gel, 0.015% and generic Ingenol Mebutate gel, 0.05% (collective, "Perrigo's ANDA Products") before the expiration of the Patents-in-Suit.

48. The 0.05% Notice Letter and the 0.015% Notice Letter state that the Paragraph IV certifications Perrigo made in the ANDAs allege that the Patents-in-Suit are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, or sale of Perrigo's ANDA Products.

49. Perrigo's 0.05% Notice Letter and 0.015% Notice Letter included an Offer of Confidential Access to the Perrigo ANDAs, subject to stated terms and restrictions. In response to the Letters, LEO sought to negotiate reasonable "restrictions as to persons entitled to access,

and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." 21 U.S.C. § 355(j)(5)(C)(i)(III). Despite good faith efforts to negotiate reasonable restrictions, LEO and Perrigo were unable to reach an agreement under which LEO could confidentially access the Perrigo ANDAs.

50. On information and belief, Perrigo UK and Perrigo Co. have assisted with and participated in the preparation and submission of the Perrigo ANDAs, have provided material support to the preparation and submission of the Perrigo ANDAs, and intend to support the further prosecution of the Perrigo ANDAs.

51. On information and belief, if FDA approves the Perrigo ANDAs, Perrigo will manufacture, offer for sale, or sell Perrigo's ANDA Products within the United States, including within Delaware, or will import Perrigo's ANDA Products into the United States, including Delaware.

52. On information and belief, if FDA approves the Perrigo ANDAs, Perrigo will actively induce or contribute to the manufacture, use, offer for sale, or sale of Perrigo's ANDA Products.

53. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within forty-five days of LEO's receipt of the 0.05% Notice Letter and the 0.015% Notice Letter.

COUNT 1: INFRINGEMENT OF THE '452 PATENT

54. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

55. On information and belief, Perrigo has submitted or caused the submission of the Perrigo ANDAs to FDA, and continues to seek FDA approval of the Perrigo ANDAs.

56. Perrigo has infringed the '452 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Perrigo ANDAs with Paragraph IV certifications and seeking FDA approval of the Perrigo ANDAs prior to the expiration of the '452 Patent.

57. The '452 Patent includes claims that recite methods of treating a subject with skin cancer comprising topically administering to the subject an amount of at least one compound selected from the group consisting of an angeloyl-substituted ingenane obtained from the sap of a *Euphorbia peplus* and an active derivative of an angeloyl-substituted ingenane obtained from the sap of *Euphorbia peplus*, wherein said active derivative exhibits the same activity as said angeloyl-substituted ingenane; such as ingenol-3-angelate.

58. On information and belief, Perrigo's ANDA Products contain ingenol-3-angelate.

59. Perrigo's commercial manufacture, use, sale offer for sale, or importation into the United States of Perrigo's ANDA Products would actively induce and/or contribute to infringement of the '452 Patent. Accordingly, unless enjoined by this Court, upon FDA approval the Perrigo ANDAs, Perrigo will make, use, offer to sell, or sell Perrigo's ANDA Products within the United States, or will import Perrigo's ANDA Products into the United States, and will thereby induce infringement and/or contribute to the infringement of one or more claims of the '452 Patent.

60. Upon information and belief, upon FDA approval of the Perrigo ANDAs, Perrigo will market and distribute Perrigo's ANDA Products to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of Perrigo's ANDA Products. On information and belief, Perrigo will also knowingly and intentionally accompany Perrigo's ANDA Products with product labels and product inserts that will include instructions for using and administering Perrigo's ANDA Products. On information and belief, the product labels and product inserts

accompanying Perrigo's ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for PICATO®, attached as Exhibit A. Accordingly, Perrigo will induce health care professionals, resellers, pharmacies, and end users of Perrigo's ANDA Products to directly infringe one or more claims of the '452 Patent. In addition, on information and belief, Perrigo will encourage acts of direct infringement with knowledge of the '452 Patent and knowledge that they are encouraging infringement.

61. Perrigo had actual and constructive notice of the '452 Patent prior to filing the Perrigo ANDAs, and was aware that the filing of the Perrigo ANDAs with the request for FDA approval prior to the expiration of the '452 Patent would constitute an act of infringement of the '452 Patent.

62. On information and belief, Perrigo filed the Perrigo ANDAs without adequate justification for asserting the '452 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Perrigo's ANDA Products. Perrigo's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '452 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

63. LEO will be irreparably harmed if Perrigo is not enjoined from infringing, and from actively inducing and/or contributing to the infringement of, the '452 Patent. LEO does not have an adequate remedy at law, and considering the balance of hardships between LEO and Perrigo, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 2: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '452 PATENT

64. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

65. LEO's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

66. The '452 Patent includes claims that recite methods of treating a subject with skin cancer comprising topically administering to the subject an amount of at least one compound selected from the group consisting of an angeloyl-substituted ingenane obtained from the sap of a *Euphorbia peplus* and an active derivative of an angeloyl-substituted ingenane obtained from the sap of *Euphorbia peplus*, wherein said active derivative exhibits the same activity as said angeloyl-substituted ingenane; such as ingenol-3-angelate.

67. On information and belief, Perrigo's ANDA Products contain ingenol-3-angelate.

68. On information and belief, if the Perrigo ANDAs are approved, Perrigo's ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Perrigo and its affiliates.

69. On information and belief, Perrigo knows that health care professionals or patients will use Perrigo's ANDA Products in accordance with the labeling sought by the Perrigo ANDAs. On information and belief, the product labels and product inserts accompanying Perrigo's ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for PICATO®, attached as Exhibit A. Therefore, Perrigo will contribute to the infringement of and/or induce the infringement of one or more claims of the '452 Patent under one or more of 35 U.S.C. §§ 271 (b) and (c).

70. On information and belief, Perrigo's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Perrigo's ANDA Products complained of herein, will begin immediately after the FDA approves the Perrigo ANDAs. Any such conduct before the '452 Patent expires will contribute to the infringement of and/or induce the

infringement of one or more claims of the ’452 Patent under one or more of 35 U.S.C. §§ 271 (b) and (c).

71. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between LEO and Perrigo concerning liability for the infringement of the ’452 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

72. LEO will be substantially and irreparably harmed by Perrigo’s infringing activities unless those activities are enjoined by this Court. LEO has no adequate remedy at law.

73. This case is exceptional, and LEO is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT 3: INFRINGEMENT OF THE ’161 PATENT

74. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

75. On information and belief, Perrigo has submitted or caused the submission of the Perrigo ANDAs to FDA, and continues to seek FDA approval of the Perrigo ANDAs.

76. Perrigo has infringed the ’161 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Perrigo ANDAs with Paragraph IV certifications and seeking FDA approval of the Perrigo ANDAs prior to the expiration of the ’161 Patent.

77. The ’161 Patent includes claims that recite methods of treating a subject with cancer, comprising administering to the subject in need thereof a therapeutically effective amount of at least one isolated compound selected from the group consisting of an angeloyl-substituted ingenane obtained from the sap of a Euphorbia species and an active derivative of an angeloyl-substituted ingenane obtained from the sap of a Euphorbia species, wherein said active

derivative exhibits the same anti-cancer activity as said angeloyl-substituted ingenane; such as ingenol-3-angelate.

78. On information and belief, Perrigo's ANDA Products contain ingenol-3-angelate.

79. Perrigo's commercial manufacture, use, sale offer for sale, or importation into the United States of Perrigo's ANDA Products would actively induce and/or contribute to infringement of the '161 Patent. Accordingly, unless enjoined by this Court, upon FDA approval the Perrigo ANDAs, Perrigo will make, use, offer to sell, or sell Perrigo's ANDA Products within the United States, or will import Perrigo's ANDA Products into the United States, and will thereby induce infringement and/or contribute to the infringement of one or more claims of the '161 Patent.

80. Upon information and belief, upon FDA approval of the Perrigo ANDAs, Perrigo will market and distribute Perrigo's ANDA Products to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of Perrigo's ANDA Products. On information and belief, Perrigo will also knowingly and intentionally accompany Perrigo's ANDA Products with product labels and product inserts that will include instructions for using and administering Perrigo's ANDA Products. On information and belief, the product labels and product inserts accompanying Perrigo's ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for PICATO®, attached as Exhibit A. Accordingly, Perrigo will induce health care professionals, resellers, pharmacies, and end users of Perrigo's ANDA Products to directly infringe one or more claims of the '161 Patent. In addition, on information and belief, Perrigo will encourage acts of direct infringement with knowledge of the '161 Patent and knowledge that they are encouraging infringement.

81. Perrigo had actual and constructive notice of the '161 Patent prior to filing the Perrigo ANDAs, and was aware that the filing of the Perrigo ANDAs with the request for FDA approval prior to the expiration of the '161 Patent would constitute an act of infringement of the '161 Patent.

82. On information and belief, Perrigo filed the Perrigo ANDAs without adequate justification for asserting the '161 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Perrigo's ANDA Products. Perrigo's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '161 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

83. LEO will be irreparably harmed if Perrigo is not enjoined from infringing, and from actively inducing and/or contributing to the infringement of, the '161 Patent. LEO does not have an adequate remedy at law, and considering the balance of hardships between LEO and Perrigo, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 4: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '161 PATENT

84. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

85. LEO's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

86. The '161 Patent includes claims that recite methods of treating a subject with cancer, comprising administering to the subject in need thereof a therapeutically effective amount of at least one isolated compound selected from the group consisting of an angeloyl-substituted ingenane obtained from the sap of a Euphorbia species and an active derivative of an

angeloyl-substituted ingenane obtained from the sap of a Euphorbia species, wherein said active derivative exhibits the same anti-cancer activity as said angeloyl-substituted ingenane; such as ingenol-3-angelate.

87. On information and belief, Perrigo's ANDA Products contain ingenol-3-angelate.

88. On information and belief, if the Perrigo ANDAs are approved, Perrigo's ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Perrigo and its affiliates.

89. On information and belief, Perrigo knows that health care professionals or patients will use Perrigo's ANDA Products in accordance with the labeling sought by the Perrigo ANDAs. On information and belief, the product labels and product inserts accompanying Perrigo's ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for PICATO®, attached as Exhibit A. Therefore, Perrigo will contribute to the infringement of and/or induce the infringement of one or more claims of the '161 Patent under one or more of 35 U.S.C. §§ 271 (b) and (c).

90. On information and belief, Perrigo's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Perrigo's ANDA Products complained of herein, will begin immediately after the FDA approves the Perrigo ANDAs. Any such conduct before the '161 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '161 Patent under one or more of 35 U.S.C. §§ 271 (b) and (c).

91. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between LEO and Perrigo concerning liability for the infringement of the

'161 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

92. LEO will be substantially and irreparably harmed by Perrigo's infringing activities unless those activities are enjoined by this Court. LEO has no adequate remedy at law.

93. This case is exceptional, and LEO is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT 5: INFRINGEMENT OF THE '013 PATENT

94. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

95. On information and belief, Perrigo has submitted or caused the submission of the Perrigo ANDAs to FDA, and continues to seek FDA approval of the Perrigo ANDAs.

96. Perrigo has infringed the '013 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Perrigo ANDAs with Paragraph IV certifications and seeking FDA approval of the Perrigo ANDAs prior to the expiration of the '013 Patent.

97. The '013 Patent includes claims that recite methods for stimulating the immune system in a human subject, comprising administering to the human subject in need thereof a therapeutically effective amount of at least one isolated compound selected from the group consisting of an angeloyl-substituted ingenane or salt thereof obtained from the sap of a Euphorbia species and an active derivative of an angeloyl-substituted ingenane or salt thereof obtained from the sap of a Euphorbia species, wherein said active derivative of an angeloyl-substituted ingenane or sale thereof exhibits the same activity as said angeloyl-substituted ingenane; such as ingenol-3-angelate.

98. On information and belief, Perrigo's ANDA Products contain ingenol-3-angelate.

99. Perrigo's commercial manufacture, use, sale offer for sale, or importation into the United States of Perrigo's ANDA Products would actively induce and/or contribute to infringement of the '013 Patent. Accordingly, unless enjoined by this Court, upon FDA approval the Perrigo ANDAs, Perrigo will make, use, offer to sell, or sell Perrigo's ANDA Products within the United States, or will import Perrigo's ANDA Products into the United States, and will thereby induce infringement and/or contribute to the infringement of one or more claims of the '013 Patent.

100. Upon information and belief, upon FDA approval of the Perrigo ANDAs, Perrigo will market and distribute Perrigo's ANDA Products to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of Perrigo's ANDA Products. On information and belief, Perrigo will also knowingly and intentionally accompany Perrigo's ANDA Products with product labels and product inserts that will include instructions for using and administering Perrigo's ANDA Products. On information and belief, the product labels and product inserts accompanying Perrigo's ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for PICATO®, attached as Exhibit A. Accordingly, Perrigo will induce health care professionals, resellers, pharmacies, and end users of Perrigo's ANDA Products to directly infringe one or more claims of the '013 Patent. In addition, on information and belief, Perrigo will encourage acts of direct infringement with knowledge of the '013 Patent and knowledge that they are encouraging infringement.

101. Perrigo had actual and constructive notice of the '013 Patent prior to filing the Perrigo ANDAs, and was aware that the filing of the Perrigo ANDAs with the request for FDA approval prior to the expiration of the '013 Patent would constitute an act of infringement of the '013 Patent.

102. On information and belief, Perrigo filed the Perrigo ANDAs without adequate justification for asserting the '013 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Perrigo's ANDA Products. Perrigo's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '013 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

103. LEO will be irreparably harmed if Perrigo is not enjoined from infringing, and from actively inducing and/or contributing to the infringement of, the '013 Patent. LEO does not have an adequate remedy at law, and considering the balance of hardships between LEO and Perrigo, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 6: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '013 PATENT

104. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

105. LEO's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

106. The '013 Patent includes claims that recite methods for stimulating the immune system in a human subject, comprising administering to the human subject in need thereof a therapeutically effective amount of at least one isolated compound selected from the group consisting of an angeloyl-substituted ingenane or salt thereof obtained from the sap of a Euphorbia species and an active derivative of an angeloyl-substituted ingenane or salt thereof obtained from the sap of a Euphorbia species, wherein said active derivative of an angeloyl-substituted ingenane or sale thereof exhibits the same activity as said angeloyl-substituted ingenane; such as ingenol-3-angelate.

107. On information and belief, Perrigo's ANDA Products contain ingenol-3-angelate.

108. On information and belief, if the Perrigo ANDAs are approved, Perrigo's ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Perrigo and its affiliates.

109. On information and belief, Perrigo knows that health care professionals or patients will use Perrigo's ANDA Products in accordance with the labeling sought by the Perrigo ANDAs. On information and belief, the product labels and product inserts accompanying Perrigo's ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for PICATO®, attached as Exhibit A. Therefore, Perrigo will contribute to the infringement of and/or induce the infringement of one or more claims of the '013 Patent under one or more of 35 U.S.C. §§ 271 (b) and (c).

110. On information and belief, Perrigo's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Perrigo's ANDA Products complained of herein, will begin immediately after the FDA approves the Perrigo ANDAs. Any such conduct before the '013 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '013 Patent under one or more of 35 U.S.C. §§ 271 (b) and (c).

111. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between LEO and Perrigo concerning liability for the infringement of the '013 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

112. LEO will be substantially and irreparably harmed by Perrigo's infringing activities unless those activities are enjoined by this Court. LEO has no adequate remedy at law.

113. This case is exceptional, and LEO is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT 7: INFRINGEMENT OF THE '656 PATENT

114. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

115. On information and belief, Perrigo has submitted or caused the submission of the Perrigo ANDAs to FDA, and continues to seek FDA approval of the Perrigo ANDAs.

116. Perrigo has infringed the '656 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Perrigo ANDAs with Paragraph IV certifications and seeking FDA approval of the Perrigo ANDAs prior to the expiration of the '656 Patent.

117. The '656 Patent includes claims that recite methods of administering an angeloyl-substituted ingenane. Ingenol-3-angelate is an angeloyl substituted ingenane.

118. On information and belief, Perrigo's ANDA Products contain ingenol-3-angelate.

119. Perrigo's commercial manufacture, use, sale offer for sale, or importation into the United States of Perrigo's ANDA Products would actively induce and/or contribute to infringement of the '656 Patent. Accordingly, unless enjoined by this Court, upon FDA approval the Perrigo ANDAs, Perrigo will make, use, offer to sell, or sell Perrigo's ANDA Products within the United States, or will import Perrigo's ANDA Products into the United States, and will thereby induce infringement and/or contribute to the infringement of one or more claims of the '656 Patent.

120. Upon information and belief, upon FDA approval of the Perrigo ANDAs, Perrigo will market and distribute Perrigo's ANDA Products to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of Perrigo's ANDA Products. On information and belief, Perrigo will also knowingly and intentionally accompany Perrigo's ANDA Products

with product labels and product inserts that will include instructions for using and administering Perrigo's ANDA Products. On information and belief, the product labels and product inserts accompanying Perrigo's ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for PICATO®, attached as Exhibit A. Accordingly, Perrigo will induce health care professionals, resellers, pharmacies, and end users of Perrigo's ANDA Products to directly infringe one or more claims of the '656 Patent. In addition, on information and belief, Perrigo will encourage acts of direct infringement with knowledge of the '656 Patent and knowledge that they are encouraging infringement.

121. Perrigo had actual and constructive notice of the '656 Patent prior to filing the Perrigo ANDAs, and was aware that the filing of the Perrigo ANDAs with the request for FDA approval prior to the expiration of the '656 Patent would constitute an act of infringement of the '656 Patent.

122. On information and belief, Perrigo filed the Perrigo ANDAs without adequate justification for asserting the '656 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Perrigo's ANDA Products. Perrigo's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '656 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

123. LEO will be irreparably harmed if Perrigo is not enjoined from infringing, and from actively inducing and/or contributing to the infringement of, the '656 Patent. LEO does not have an adequate remedy at law, and considering the balance of hardships between LEO and Perrigo, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 8: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '656 PATENT

124. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

125. LEO's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

126. The '656 Patent includes claims that recite methods of administering an angeloyl-substituted ingenane. Ingenol-3-angelate is an angeloyl substituted ingenane.

127. On information and belief, Perrigo's ANDA Products contain ingenol-3-angelate.

128. On information and belief, if the Perrigo ANDAs are approved, Perrigo's ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Perrigo and its affiliates.

129. On information and belief, Perrigo knows that health care professionals or patients will use Perrigo's ANDA Products in accordance with the labeling sought by the Perrigo ANDAs. On information and belief, the product labels and product inserts accompanying Perrigo's ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for PICATO®, attached as Exhibit A. Therefore, Perrigo will contribute to the infringement of and/or induce the infringement of one or more claims of the '656 Patent under one or more of 35 U.S.C. §§ 271 (b) and (c).

130. On information and belief, Perrigo's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Perrigo's ANDA Products complained of herein, will begin immediately after the FDA approves the Perrigo ANDAs. Any such conduct before the '656 Patent expires will contribute to the infringement of and/or induce the

infringement of one or more claims of the ’656 Patent under one or more of 35 U.S.C. §§ 271 (b) and (c).

131. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between LEO and Perrigo concerning liability for the infringement of the ’656 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

132. LEO will be substantially and irreparably harmed by Perrigo’s infringing activities unless those activities are enjoined by this Court. LEO has no adequate remedy at law.

133. This case is exceptional, and LEO is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT 9: INFRINGEMENT OF THE ’292 PATENT

134. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

135. On information and belief, Perrigo has submitted or caused the submission of the Perrigo ANDAs to FDA, and continues to seek FDA approval of the Perrigo ANDAs.

136. Perrigo has infringed the ’292 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Perrigo ANDAs with Paragraph IV certifications and seeking FDA approval of the Perrigo ANDAs prior to the expiration of the ’292 Patent.

137. The ’292 Patent includes claims that recite a pharmaceutical formulation comprising ingenol-3-angelate and a pharmaceutically acceptable solvent, wherein the pharmaceutical formulation retains specified amounts of ingenol-3-angelate under certain duration and temperature conditions.

138. On information and belief, Perrigo’s ANDA Products contain a pharmaceutical formulation comprising ingenol-3-angelate and a pharmaceutically acceptable solvent, wherein

the pharmaceutical formulation retains specified amounts of ingenol-3-angelate at certain duration and temperature conditions.

139. Perrigo's commercial manufacture, use, sale offer for sale, or importation into the United States of Perrigo's ANDA Products would directly infringe, and/or would actively induce and/or contribute to infringement of, the '292 Patent. Upon information and belief, upon FDA approval of the Perrigo ANDAs, Perrigo will market and distribute Perrigo's ANDA Products to third parties including resellers, pharmacies, hospitals and other clinics. Accordingly, unless enjoined by this Court, upon FDA approval of the Perrigo ANDAs, Perrigo will make, use, offer to sell, or sell Perrigo's ANDA Products within the United States, or will import Perrigo's ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '292 Patent.

140. Perrigo had actual and constructive notice of the '292 Patent prior to filing the Perrigo ANDAs, and was aware that the filing of the Perrigo ANDAs with the request for FDA approval prior to the expiration of the '292 Patent would constitute an act of infringement of the '292 Patent.

141. In the 0.05% Notice Letter and 0.015% Notice Letter, Perrigo does not allege non-infringement for one or more claims, as written, of the '292 Patent.

142. On information and belief, Perrigo filed the Perrigo ANDAs without adequate justification for asserting the '292 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Perrigo's ANDA Products. Perrigo's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '292 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

143. LEO will be irreparably harmed if Perrigo is not enjoined from infringing, and from actively inducing and/or contributing to the infringement of, the '292 Patent. LEO does not have an adequate remedy at law, and considering the balance of hardships between LEO and Perrigo, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 10: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '292 PATENT

144. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

145. LEO's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

146. The '292 Patent includes claims that recite a pharmaceutical formulation comprising ingenol-3-angelate and a pharmaceutically acceptable solvent, wherein the pharmaceutical formulation retains specified amounts of ingenol-3-angelate under certain duration and temperature conditions.

147. On information and belief, Perrigo's ANDA Products contain a pharmaceutical formulation comprising ingenol-3-angelate and a pharmaceutically acceptable solvent, wherein the pharmaceutical formulation retains specified amounts of ingenol-3-angelate at certain duration and temperature conditions.

148. On information and belief, if the Perrigo ANDAs are approved, Perrigo's ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Perrigo and its affiliates.

149. On information and belief, if the Perrigo ANDAs are approved, Perrigo's ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States,

including in the State of Delaware, by or through Perrigo and its affiliates. Perrigo will therefore infringe one or more claims of the '292 Patent under 35 U.S.C. § 271(a).

150. On information and belief, Perrigo's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Perrigo's ANDA Products complained of herein, will begin immediately after the FDA approves the Perrigo ANDAs. Any such conduct before the '292 Patent expires will infringe, contribute to the infringement of and/or induce the infringement of one or more claims of the '292 Patent under one or more of 35 U.S.C. §§ 271 (a), (b) and (c).

151. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between LEO and Perrigo concerning liability for the infringement of the '292 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

152. LEO will be substantially and irreparably harmed by Perrigo's infringing activities unless those activities are enjoined by this Court. LEO has no adequate remedy at law.

153. This case is exceptional, and LEO is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT 11: INFRINGEMENT OF THE '827 PATENT

154. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

155. On information and belief, Perrigo has submitted or caused the submission of the Perrigo ANDAs to FDA, and continues to seek FDA approval of the Perrigo ANDAs.

156. Perrigo has infringed the '827 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Perrigo ANDAs with Paragraph IV certifications and seeking FDA approval of the Perrigo ANDAs prior to the expiration of the '827 Patent.

157. The ’827 Patent includes claims that recite a pharmaceutical formulation comprising ingenol angelate, wherein a specified quantity of the ingenol angelate is ingenol-3-angelate, and said pharmaceutical formulation has a specified pH range.

158. On information and belief, Perrigo’s ANDA Products contain a pharmaceutical formulation comprising ingenol angelate, wherein the specified quantity of the ingenol angelate is ingenol-3-angelate, and said pharmaceutical formulation has the specified pH range.

159. Perrigo’s commercial manufacture, use, sale offer for sale, or importation into the United States of Perrigo’s ANDA Products would directly infringe, and/or would actively induce and/or contribute to infringement of the ’827 Patent. Upon information and belief, upon FDA approval of the Perrigo ANDAs, Perrigo will market and distribute Perrigo’s ANDA Products to third parties including resellers, pharmacies, hospitals and other clinics. Accordingly, unless enjoined by this Court, upon FDA approval of the Perrigo ANDAs, Perrigo will make, use, offer to sell, or sell Perrigo’s ANDA Products within the United States, or will import Perrigo’s ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’827 Patent.

160. Perrigo had actual and constructive notice of the ’827 Patent prior to filing the Perrigo ANDAs, and was aware that the filing of the Perrigo ANDAs with the request for FDA approval prior to the expiration of the ’827 Patent would constitute an act of infringement of the ’827 Patent.

161. On information and belief, Perrigo filed the Perrigo ANDAs without adequate justification for asserting the ’827 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Perrigo’s ANDA Products. Perrigo’s

conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '827 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

162. LEO will be irreparably harmed if Perrigo is not enjoined from infringing, and from actively inducing and/or contributing to the infringement of, the '827 Patent. LEO does not have an adequate remedy at law, and considering the balance of hardships between LEO and Perrigo, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 12: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '827 PATENT

163. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

164. LEO's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

165. The '827 Patent includes claims that recite a pharmaceutical formulation comprising ingenol angelate, wherein a specified quantity of the ingenol angelate is ingenol-3-angelate, and said pharmaceutical formulation has a specified pH range.

166. On information and belief, Perrigo's ANDA Products contain a pharmaceutical formulation comprising ingenol angelate, wherein the specified quantity of the ingenol angelate is ingenol-3-angelate, and said pharmaceutical formulation has the specified pH range.

167. On information and belief, if the Perrigo ANDAs are approved, Perrigo's ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Perrigo and its affiliates.

168. On information and belief, if the Perrigo ANDAs are approved, Perrigo's ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States,

including in the State of Delaware, by or through Perrigo and its affiliates. Perrigo will therefore infringe one or more claims of the '827 Patent under 35 U.S.C. § 271(a).

169. On information and belief, Perrigo's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Perrigo's ANDA Products complained of herein, will begin immediately after the FDA approves the Perrigo ANDAs. Any such conduct before the '827 Patent expires will infringe, contribute to the infringement of and/or induce the infringement of one or more claims of the '827 Patent under one or more of 35 U.S.C. §§ 271 (a), (b) and (c).

170. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between LEO and Perrigo concerning liability for the infringement of the '827 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

171. LEO will be substantially and irreparably harmed by Perrigo's infringing activities unless those activities are enjoined by this Court. LEO has no adequate remedy at law.

172. This case is exceptional, and LEO is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT 13: INFRINGEMENT OF THE '828 PATENT

173. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

174. On information and belief, Perrigo has submitted or caused the submission of the Perrigo ANDAs to FDA, and continues to seek FDA approval of the Perrigo ANDAs.

175. Perrigo has infringed the '828 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Perrigo ANDAs with Paragraph IV certifications and seeking FDA approval of the Perrigo ANDAs prior to the expiration of the '828 Patent.

176. The ’828 Patent includes claims that recite a pharmaceutical formulation comprising ingenol angelate, wherein a specified quantity of the ingenol angelate is ingenol-3-angelate, and said pharmaceutical formulation has a specified pH range.

177. On information and belief, Perrigo’s ANDA Products contain a pharmaceutical formulation comprising ingenol angelate, wherein the specified quantity of the ingenol angelate is ingenol-3-angelate, and said pharmaceutical formulation has the specified pH range.

178. Perrigo’s commercial manufacture, use, sale offer for sale, or importation into the United States of Perrigo’s ANDA Products would directly infringe, and/or would actively induce and/or contribute to infringement of the ’828 Patent. Upon information and belief, upon FDA approval of the Perrigo ANDAs, Perrigo will market and distribute Perrigo’s ANDA Products to third parties including resellers, pharmacies, hospitals and other clinics. Accordingly, unless enjoined by this Court, upon FDA approval of the Perrigo ANDAs, Perrigo will make, use, offer to sell, or sell Perrigo’s ANDA Products within the United States, or will import Perrigo’s ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’828 Patent.

179. Perrigo had actual and constructive notice of the ’828 Patent prior to filing the Perrigo ANDAs, and was aware that the filing of the Perrigo ANDAs with the request for FDA approval prior to the expiration of the ’828 Patent would constitute an act of infringement of the ’828 Patent.

180. On information and belief, Perrigo filed the Perrigo ANDAs without adequate justification for asserting the ’828 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Perrigo’s ANDA Products. Perrigo’s

conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '828 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

181. LEO will be irreparably harmed if Perrigo is not enjoined from infringing, and from actively inducing and/or contributing to the infringement of, the '828 Patent. LEO does not have an adequate remedy at law, and considering the balance of hardships between LEO and Perrigo, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 14: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '828 PATENT

182. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

183. LEO's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

184. The '828 Patent includes claims that recite a pharmaceutical formulation comprising ingenol angelate, wherein a specified quantity of the ingenol angelate is ingenol-3-angelate, and said pharmaceutical formulation has a specified pH range.

185. On information and belief, Perrigo's ANDA Products contain a pharmaceutical formulation comprising ingenol angelate, wherein the specified quantity of the ingenol angelate is ingenol-3-angelate, and said pharmaceutical formulation has the specified pH range.

186. On information and belief, if the Perrigo ANDAs are approved, Perrigo's ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Perrigo and its affiliates.

187. On information and belief, if the Perrigo ANDAs are approved, Perrigo's ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States,

including in the State of Delaware, by or through Perrigo and its affiliates. Perrigo will therefore infringe one or more claims of the '828 Patent under 35 U.S.C. § 271(a).

188. On information and belief, Perrigo's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Perrigo's ANDA Products complained of herein, will begin immediately after the FDA approves the Perrigo ANDAs. Any such conduct before the '828 Patent expires will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '828 Patent under one or more of 35 U.S.C. §§ 271 (a), (b) and (c).

189. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between LEO and Perrigo concerning liability for the infringement of the '828 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

190. LEO will be substantially and irreparably harmed by Perrigo's infringing activities unless those activities are enjoined by this Court. LEO has no adequate remedy at law.

191. This case is exceptional, and LEO is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT 15: INFRINGEMENT OF THE '919 PATENT

192. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

193. On information and belief, Perrigo has submitted or caused the submission of the Perrigo ANDAs to FDA, and continues to seek FDA approval of the Perrigo ANDAs.

194. Perrigo has infringed the '919 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Perrigo ANDAs with Paragraph IV certifications and seeking FDA approval of the Perrigo ANDAs prior to the expiration of the '919 Patent.

195. The ’919 Patent includes claims that recite a pharmaceutical formulation comprising ingenol angelate, wherein a specified quantity of the ingenol angelate is ingenol-3-angelate, and said pharmaceutical formulation has a specified pH range.

196. On information and belief, Perrigo’s ANDA Products contain a pharmaceutical formulation comprising ingenol angelate, wherein the specified quantity of the ingenol angelate is ingenol-3-angelate, and said pharmaceutical formulation has the specified pH range.

197. Perrigo’s commercial manufacture, use, sale offer for sale, or importation into the United States of Perrigo’s ANDA Products would directly infringe, and/or would actively induce and/or contribute to infringement of, the ’919 Patent. Upon information and belief, upon FDA approval of the Perrigo ANDAs, Perrigo will market and distribute Perrigo’s ANDA Products to third parties including resellers, pharmacies, hospitals and other clinics. Accordingly, unless enjoined by this Court, upon FDA approval of the Perrigo ANDAs, Perrigo will make, use, offer to sell, or sell Perrigo’s ANDA Products within the United States, or will import Perrigo’s ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’919 Patent.

198. Perrigo had actual and constructive notice of the ’919 Patent prior to filing the Perrigo ANDAs, and was aware that the filing of the Perrigo ANDAs with the request for FDA approval prior to the expiration of the ’919 Patent would constitute an act of infringement of the ’919 Patent.

199. On information and belief, Perrigo filed the Perrigo ANDAs without adequate justification for asserting the ’919 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Perrigo’s ANDA Products. Perrigo’s

conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '919 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

200. LEO will be irreparably harmed if Perrigo is not enjoined from infringing, and from actively inducing and/or contributing to the infringement of, the '919 Patent. LEO does not have an adequate remedy at law, and considering the balance of hardships between LEO and Perrigo, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 16: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '919 PATENT

201. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

202. LEO's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

203. The '919 Patent includes claims that recite a pharmaceutical formulation comprising ingenol angelate, wherein a specified quantity of the ingenol angelate is ingenol-3-angelate, and said pharmaceutical formulation has a specified pH range.

204. On information and belief, Perrigo's ANDA Products contain a pharmaceutical formulation comprising ingenol angelate, wherein the specified quantity of the ingenol angelate is ingenol-3-angelate, and said pharmaceutical formulation has the specified pH range.

205. On information and belief, if the Perrigo ANDAs are approved, Perrigo's ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Perrigo and its affiliates.

206. On information and belief, if the Perrigo ANDAs are approved, Perrigo's ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States,

including in the State of Delaware, by or through Perrigo and its affiliates. Perrigo will therefore infringe one or more claims of the '919 Patent under 35 U.S.C. § 271(a).

207. On information and belief, Perrigo's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Perrigo's ANDA Products complained of herein, will begin immediately after the FDA approves the Perrigo ANDAs. Any such conduct before the '919 Patent expires will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '919 Patent under one or more of 35 U.S.C. §§ 271 (a), (b) and (c).

208. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between LEO and Perrigo concerning liability for the infringement of the '919 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

209. LEO will be substantially and irreparably harmed by Perrigo's infringing activities unless those activities are enjoined by this Court. LEO has no adequate remedy at law.

210. This case is exceptional, and LEO is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT 17: INFRINGEMENT OF THE '163 PATENT

211. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

212. On information and belief, Perrigo has submitted or caused the submission of the Perrigo ANDAs to FDA, and continues to seek FDA approval of the Perrigo ANDAs.

213. Perrigo has infringed the '163 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Perrigo ANDAs with Paragraph IV certifications and seeking FDA approval of the Perrigo ANDAs prior to the expiration of the '163 Patent.

214. The ’163 Patent includes claims that recite methods of administering a pharmaceutical formulation comprising ingenol angelate, wherein a specified quantity of the ingenol angelate is ingenol-3-angelate, and said pharmaceutical formulation has a specified pH range.

215. On information and belief, Perrigo’s ANDA Products contain a pharmaceutical formulation comprising ingenol angelate, wherein the specified quantity of the ingenol angelate is ingenol-3-angelate, and said pharmaceutical formulation has the specified pH range.

216. Perrigo’s commercial manufacture, use, sale offer for sale, or importation into the United States of Perrigo’s ANDA Products would actively induce and/or contribute to infringement of the ’163 Patent. Accordingly, unless enjoined by this Court, upon FDA approval the Perrigo ANDAs, Perrigo will make, use, offer to sell, or sell Perrigo’s ANDA Products within the United States, or will import Perrigo’s ANDA Products into the United States, and will thereby induce infringement and/or contribute to the infringement of one or more claims of the ’163 Patent.

217. Upon information and belief, upon FDA approval of the Perrigo ANDAs, Perrigo will market and distribute Perrigo’s ANDA Products to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of Perrigo’s ANDA Products. On information and belief, Perrigo will also knowingly and intentionally accompany Perrigo’s ANDA Products with product labels and product inserts that will include instructions for using and administering Perrigo’s ANDA Products. On information and belief, the product labels and product inserts accompanying Perrigo’s ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for PICATO®, attached as Exhibit A. Accordingly, Perrigo will induce health care professionals, resellers, pharmacies, and end users

of Perrigo's ANDA Products to directly infringe one or more claims of the '163 Patent. In addition, on information and belief, Perrigo will encourage acts of direct infringement with knowledge of the '163 Patent and knowledge that they are encouraging infringement.

218. Perrigo had actual and constructive notice of the '163 Patent prior to filing the Perrigo ANDAs, and was aware that the filing of the Perrigo ANDAs with the request for FDA approval prior to the expiration of the '163 Patent would constitute an act of infringement of the '163 Patent.

219. On information and belief, Perrigo filed the Perrigo ANDAs without adequate justification for asserting the '163 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Perrigo's ANDA Products. Perrigo's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '163 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

220. LEO will be irreparably harmed if Perrigo is not enjoined from infringing, and from actively inducing and/or contributing to the infringement of, the '163 Patent. LEO does not have an adequate remedy at law, and considering the balance of hardships between LEO and Perrigo, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 18: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '163 PATENT

221. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

222. LEO's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

223. The ’163 Patent includes claims that recite methods of administering a pharmaceutical formulation comprising ingenol angelate, wherein a specified quantity of the ingenol angelate is ingenol-3-angelate, and said pharmaceutical formulation has a specified pH range.

224. On information and belief, Perrigo’s ANDA Products contain a pharmaceutical formulation comprising ingenol angelate, wherein the specified quantity of the ingenol angelate is ingenol-3-angelate, and said pharmaceutical formulation has the specified pH range.

225. On information and belief, if the Perrigo ANDAs are approved, Perrigo’s ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Perrigo and its affiliates.

226. On information and belief, Perrigo knows that health care professionals or patients will use Perrigo’s ANDA Products in accordance with the labeling sought by the Perrigo ANDAs. On information and belief, the product labels and product inserts accompanying Perrigo’s ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for PICATO®, attached as Exhibit A. Therefore, Perrigo will contribute to the infringement of and/or induce the infringement of one or more claims of the ’163 Patent under one or more of 35 U.S.C. §§ 271 (b) and (c).

227. On information and belief, Perrigo’s infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Perrigo’s ANDA Products complained of herein, will begin immediately after the FDA approves the Perrigo ANDAs. Any such conduct before the ’163 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the ’163 Patent under one or more of 35 U.S.C. §§ 271 (b) and (c).

228. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between LEO and Perrigo concerning liability for the infringement of the '163 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

229. LEO will be substantially and irreparably harmed by Perrigo's infringing activities unless those activities are enjoined by this Court. LEO has no adequate remedy at law.

230. This case is exceptional, and LEO is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT 19: INFRINGEMENT OF THE '271 PATENT

231. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

232. On information and belief, Perrigo has submitted or caused the submission of the Perrigo ANDAs to FDA, and continues to seek FDA approval of the Perrigo ANDAs.

233. Perrigo has infringed the '271 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Perrigo ANDAs with Paragraph IV certifications and seeking FDA approval of the Perrigo ANDAs prior to the expiration of the '271 Patent.

234. The '271 Patent includes claims that recite methods of administering a pharmaceutical formulation comprising ingenol angelate, wherein a specified quantity of the ingenol angelate is ingenol-3-angelate, and said pharmaceutical formulation has a specified pH range.

235. On information and belief, Perrigo's ANDA Products contain a pharmaceutical formulation comprising ingenol angelate, wherein the specified quantity of the ingenol angelate is ingenol-3-angelate, and said pharmaceutical formulation has the specified pH range.

236. Perrigo's commercial manufacture, use, sale offer for sale, or importation into the United States of Perrigo's ANDA Products would actively induce and/or contribute to infringement of the '271 Patent. Accordingly, unless enjoined by this Court, upon FDA approval the Perrigo ANDAs, Perrigo will make, use, offer to sell, or sell Perrigo's ANDA Products within the United States, or will import Perrigo's ANDA Products into the United States, and will thereby induce infringement and/or contribute to the infringement of one or more claims of the '271 Patent.

237. Upon information and belief, upon FDA approval of the Perrigo ANDAs, Perrigo will market and distribute Perrigo's ANDA Products to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of Perrigo's ANDA Products. On information and belief, Perrigo will also knowingly and intentionally accompany Perrigo's ANDA Products with product labels and product inserts that will include instructions for using and administering Perrigo's ANDA Products. On information and belief, the product labels and product inserts accompanying Perrigo's ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for PICATO®, attached as Exhibit A. Accordingly, Perrigo will induce health care professionals, resellers, pharmacies, and end users of Perrigo's ANDA Products to directly infringe one or more claims of the '271 Patent. In addition, on information and belief, Perrigo will encourage acts of direct infringement with knowledge of the '271 Patent and knowledge that they are encouraging infringement.

238. Perrigo had actual and constructive notice of the '271 Patent prior to filing the Perrigo ANDAs, and was aware that the filing of the Perrigo ANDAs with the request for FDA approval prior to the expiration of the '271 Patent would constitute an act of infringement of the '271 Patent.

239. On information and belief, Perrigo filed the Perrigo ANDAs without adequate justification for asserting the '271 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Perrigo's ANDA Products. Perrigo's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '271 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

240. LEO will be irreparably harmed if Perrigo is not enjoined from infringing, and from actively inducing and/or contributing to the infringement of, the '271 Patent. LEO does not have an adequate remedy at law, and considering the balance of hardships between LEO and Perrigo, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 20: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '271 PATENT

241. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

242. LEO's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

243. The '271 Patent includes claims that recite methods of administering a pharmaceutical formulation comprising ingenol angelate, wherein a specified quantity of the ingenol angelate is ingenol-3-angelate, and said pharmaceutical formulation has a specified pH range.

244. On information and belief, Perrigo's ANDA Products contain a pharmaceutical formulation comprising ingenol angelate, wherein the specified quantity of the ingenol angelate is ingenol-3-angelate, and said pharmaceutical formulation has the specified pH range.

245. On information and belief, if the Perrigo ANDAs are approved, Perrigo's ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Perrigo and its affiliates.

246. On information and belief, Perrigo knows that health care professionals or patients will use Perrigo's ANDA Products in accordance with the labeling sought by the Perrigo ANDAs. On information and belief, the product labels and product inserts accompanying Perrigo's ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for PICATO®, attached as Exhibit A. Therefore, Perrigo will contribute to the infringement of and/or induce the infringement of one or more claims of the '271 Patent under one or more of 35 U.S.C. §§ 271 (b) and (c).

247. On information and belief, Perrigo's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Perrigo's ANDA Products complained of herein, will begin immediately after the FDA approves the Perrigo ANDAs. Any such conduct before the '271 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '271 Patent under one or more of 35 U.S.C. §§ 271 (b) and (c).

248. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between LEO and Perrigo concerning liability for the infringement of the '271 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

249. LEO will be substantially and irreparably harmed by Perrigo's infringing activities unless those activities are enjoined by this Court. LEO has no adequate remedy at law.

250. This case is exceptional, and LEO is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT 21: INFRINGEMENT OF THE '375 PATENT

251. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

252. On information and belief, Perrigo has submitted or caused the submission of the Perrigo ANDAs to FDA, and continues to seek FDA approval of the Perrigo ANDAs.

253. Perrigo has infringed the '375 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Perrigo ANDAs with Paragraph IV certifications and seeking FDA approval of the Perrigo ANDAs prior to the expiration of the '375 Patent.

254. The '375 Patent includes claims that recite methods of administering a pharmaceutical formulation comprising ingenol angelate, wherein a specified quantity of the ingenol angelate is ingenol-3-angelate, and said pharmaceutical formulation has a specified pH range.

255. On information and belief, Perrigo's ANDA Products contain a pharmaceutical formulation comprising ingenol angelate, wherein the specified quantity of the ingenol angelate is ingenol-3-angelate, and said pharmaceutical formulation has the specified pH range.

256. Perrigo's commercial manufacture, use, sale offer for sale, or importation into the United States of Perrigo's ANDA Products would actively induce and/or contribute to infringement of the '375 Patent. Accordingly, unless enjoined by this Court, upon FDA approval the Perrigo ANDAs, Perrigo will make, use, offer to sell, or sell Perrigo's ANDA Products within the United States, or will import Perrigo's ANDA Products into the United States, and will thereby induce infringement and/or contribute to the infringement of one or more claims of the '375 Patent.

257. Upon information and belief, upon FDA approval of the Perrigo ANDAs, Perrigo will market and distribute Perrigo's ANDA Products to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of Perrigo's ANDA Products. On information and belief, Perrigo will also knowingly and intentionally accompany Perrigo's ANDA Products with product labels and product inserts that will include instructions for using and administering Perrigo's ANDA Products. On information and belief, the product labels and product inserts accompanying Perrigo's ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for PICATO®, attached as Exhibit A. Accordingly, Perrigo will induce health care professionals, resellers, pharmacies, and end users of Perrigo's ANDA Products to directly infringe one or more claims of the '375 Patent. In addition, on information and belief, Perrigo will encourage acts of direct infringement with knowledge of the '375 Patent and knowledge that they are encouraging infringement.

258. Perrigo had actual and constructive notice of the '375 Patent prior to filing the Perrigo ANDAs, and was aware that the filing of the Perrigo ANDAs with the request for FDA approval prior to the expiration of the '375 Patent would constitute an act of infringement of the '375 Patent.

259. On information and belief, Perrigo filed the Perrigo ANDAs without adequate justification for asserting the '375 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Perrigo's ANDA Products. Perrigo's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '375 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

260. LEO will be irreparably harmed if Perrigo is not enjoined from infringing, and from actively inducing and/or contributing to the infringement of, the '375 Patent. LEO does not

have an adequate remedy at law, and considering the balance of hardships between LEO and Perrigo, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 22: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '375 PATENT

261. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

262. LEO's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

263. The '375 Patent includes claims that recite methods of administering a pharmaceutical formulation comprising ingenol angelate, wherein a specified quantity of the ingenol angelate is ingenol-3-angelate, and said pharmaceutical formulation has a specified pH range.

264. On information and belief, Perrigo's ANDA Products contain a pharmaceutical formulation comprising ingenol angelate, wherein the specified quantity of the ingenol angelate is ingenol-3-angelate, and said pharmaceutical formulation has the specified pH range.

265. On information and belief, if the Perrigo ANDAs are approved, Perrigo's ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Perrigo and its affiliates.

266. On information and belief, Perrigo knows that health care professionals or patients will use Perrigo's ANDA Products in accordance with the labeling sought by the Perrigo ANDAs. On information and belief, the product labels and product inserts accompanying Perrigo's ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for PICATO®, attached as Exhibit A.

Therefore, Perrigo will contribute to the infringement of and/or induce the infringement of one or more claims of the '375 Patent under one or more of 35 U.S.C. §§ 271 (b) and (c).

267. On information and belief, Perrigo's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Perrigo's ANDA Products complained of herein, will begin immediately after the FDA approves the Perrigo ANDAs. Any such conduct before the '375 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '375 Patent under one or more of 35 U.S.C. §§ 271 (b) and (c).

268. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between LEO and Perrigo concerning liability for the infringement of the '375 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

269. LEO will be substantially and irreparably harmed by Perrigo's infringing activities unless those activities are enjoined by this Court. LEO has no adequate remedy at law.

270. This case is exceptional, and LEO is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, LEO seeks the following relief:

A. A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A) Perrigo's submission to the FDA of ANDA Nos. 209018 and 209019 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Perrigo's ANDA Products before the expiration of the '452 Patent was an act of infringement of one or more claims of the '452 Patent;

B. A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A) Perrigo's submission to the FDA of ANDA Nos. 209018 and 209019 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Perrigo's ANDA Products before the expiration of the '161 Patent was an act of infringement of one or more claims of the '161 Patent;

C. A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A) Perrigo's submission to the FDA of ANDA Nos. 209018 and 209019 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Perrigo's ANDA Products before the expiration of the '013 Patent was an act of infringement of one or more claims of the '013 Patent;

D. A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A) Perrigo's submission to the FDA of ANDA Nos. 209018 and 209019 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Perrigo's ANDA Products before the expiration of the '656 Patent was an act of infringement of one or more claims of the '656 Patent;

E. A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A) Perrigo's submission to the FDA of ANDA Nos. 209018 and 209019 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Perrigo's ANDA Products before the expiration of the '292 Patent was an act of infringement of one or more claims of the '292 Patent;

F. A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A) Perrigo's submission to the FDA of ANDA Nos. 209018 and 209019 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Perrigo's

ANDA Products before the expiration of the ’827 Patent was an act of infringement of one or more claims of the ’827 Patent;

G. A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A) Perrigo’s submission to the FDA of ANDA Nos. 209018 and 209019 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Perrigo’s ANDA Products before the expiration of the ’828 Patent was an act of infringement of one or more claims of the ’828 Patent;

H. A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A) Perrigo’s submission to the FDA of ANDA Nos. 209018 and 209019 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Perrigo’s ANDA Products before the expiration of the ’919 Patent was an act of infringement of one or more claims of the ’919 Patent;

I. A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A) Perrigo’s submission to the FDA of ANDA Nos. 209018 and 209019 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Perrigo’s ANDA Products before the expiration of the ’163 Patent was an act of infringement of one or more claims of the ’163 Patent;

J. A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A) Perrigo’s submission to the FDA of ANDA Nos. 209018 and 209019 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Perrigo’s ANDA Products before the expiration of the ’271 Patent was an act of infringement of one or more claims of the ’271 Patent;

K. A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A) Perrigo's submission to the FDA of ANDA Nos. 209018 and 209019 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Perrigo's ANDA Products before the expiration of the '375 Patent was an act of infringement of one or more claims of the '375 Patent;

L. A declaratory judgment that under one or more of 35 U.S.C. § 271(a), (b) and (c), Perrigo's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Perrigo's ANDA Products, or inducing or contributing to such conduct, would constitute of infringement of one or more claims of the '452 Patent;

M. A declaratory judgment that under one or more of 35 U.S.C. § 271(a), (b) and (c), Perrigo's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Perrigo's ANDA Products, or inducing or contributing to such conduct, would constitute of infringement of one or more claims of the '161 Patent;

N. A declaratory judgment that under one or more of 35 U.S.C. § 271(a), (b) and (c), Perrigo's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Perrigo's ANDA Products, or inducing or contributing to such conduct, would constitute of infringement of one or more claims of the '013 Patent;

O. A declaratory judgment that under one or more of 35 U.S.C. § 271(a), (b) and (c), Perrigo's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Perrigo's ANDA Products, or inducing or contributing to such conduct, would constitute of infringement of one or more claims of the '656 Patent;

P. A declaratory judgment that under one or more of 35 U.S.C. § 271(a), (b) and (c), Perrigo's commercial manufacture, use, offer for sale, or sale in, or importation into, the United

States of the Perrigo's ANDA Products, or inducing or contributing to such conduct, would constitute of infringement of one or more claims of the '292 Patent;

Q. A declaratory judgment that under one or more of 35 U.S.C. § 271(a), (b) and (c), Perrigo's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Perrigo's ANDA Products, or inducing or contributing to such conduct, would constitute of infringement of one or more claims of the '827 Patent;

R. A declaratory judgment that under one or more of 35 U.S.C. § 271(a), (b) and (c), Perrigo's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Perrigo's ANDA Products, or inducing or contributing to such conduct, would constitute of infringement of one or more claims of the '828 Patent;

S. A declaratory judgment that under one or more of 35 U.S.C. § 271(a), (b) and (c), Perrigo's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Perrigo's ANDA Products, or inducing or contributing to such conduct, would constitute of infringement of one or more claims of the '919 Patent;

T. A declaratory judgment that under one or more of 35 U.S.C. § 271(a), (b) and (c), Perrigo's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Perrigo's ANDA Products, or inducing or contributing to such conduct, would constitute of infringement of one or more claims of the '163 Patent;

U. A declaratory judgment that under one or more of 35 U.S.C. § 271(a), (b) and (c), Perrigo's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Perrigo's ANDA Products, or inducing or contributing to such conduct, would constitute of infringement of one or more claims of the '271 Patent;

V. A declaratory judgment that under one or more of 35 U.S.C. § 271(a), (b) and (c), Perrigo's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Perrigo's ANDA Products, or inducing or contributing to such conduct, would constitute of infringement of one or more claims of the '375 Patent;

W. The entry of a permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), enjoining Perrigo, its affiliates and subsidiaries, and all persons and entities acting in concert with Perrigo from commercially manufacturing, using, offering for sale, or selling Perrigo's ANDA Products within the United States, or importing Perrigo's ANDA Products into the United States, until the expiration of the Patents-in-Suit;

X. The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of ANDA Nos. 209018 and 209019 shall be no earlier than the last expiration of any of the Patents-in-Suit, or any later expiration of exclusivity for any of the Patents-in-Suit, including any extensions or regulatory exclusivities;

Y. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Perrigo engages in the commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo's ANDA Products, or any product that infringes the '452 Patent, or induces or contributes to such conduct, prior to the expiration of the '452 Patent;

Z. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Perrigo engages in the commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo's ANDA Products, or any product that infringes the '161 Patent, or induces or contributes to such conduct, prior to the expiration of the '161 Patent;

AA. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Perrigo engages in the commercial manufacture, use, offer for sale, sale, and/or importation of

Perrigo's ANDA Products, or any product that infringes the '013 Patent, or induces or contributes to such conduct, prior to the expiration of the '013 Patent;

BB. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Perrigo engages in the commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo's ANDA Products, or any product that infringes the '656 Patent, or induces or contributes to such conduct, prior to the expiration of the '656 Patent;

CC. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Perrigo engages in the commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo's ANDA Products, or any product that infringes the '292 Patent, or induces or contributes to such conduct, prior to the expiration of the '292 Patent;

DD. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Perrigo engages in the commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo's ANDA Products, or any product that infringes the '827 Patent, or induces or contributes to such conduct, prior to the expiration of the '827 Patent;

EE. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Perrigo engages in the commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo's ANDA Products, or any product that infringes the '828 Patent, or induces or contributes to such conduct, prior to the expiration of the '828 Patent;

FF. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Perrigo engages in the commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo's ANDA Products, or any product that infringes the '919 Patent, or induces or contributes to such conduct, prior to the expiration of the '919 Patent;

GG. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Perrigo engages in the commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo's ANDA Products, or any product that infringes the '163 Patent, or induces or contributes to such conduct, prior to the expiration of the '163 Patent;

HH. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Perrigo engages in the commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo's ANDA Products, or any product that infringes the '271 Patent, or induces or contributes to such conduct, prior to the expiration of the '271 Patent;

II. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Perrigo engages in the commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo's ANDA Products, or any product that infringes the '375 Patent, or induces or contributes to such conduct, prior to the expiration of the '375 Patent;

JJ. The entry of judgment declaring that Perrigo's acts render this an exceptional case, and awarding LEO attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

KK. An award to LEO of its costs and expenses in this action; and

LL. Such further and other relief as this Court determines to be just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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June 10, 2016